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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,888	11/20/2000	Andrew C. Hiatt	030905.0002.CON2	6791

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EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 08/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/717,888	Hiatt et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Jul 18, 2002* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *54-82* is/are pending in the application.

4a) Of the above, claim(s) *54-79 and 81* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *80 and 82* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [✓] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Response to Amendment

The receipt of Third preliminary amendment of 7/18/02 is acknowledged. Claim 82 has been added. Claims 54-82 are pending before the examiner.

Election/Restriction

Applicant's election with traverse of Group IX (claim 80) in Paper No. 11 is acknowledged. However, since no argument was set forth by the applicants the election was treated as an Election **without** traverse. Hence, claims 54-79, and 81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected . Claims 80, and 82 are considered on the merit.

Applicants are reminded to cancel the claims to the non elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Please update the current status of all priority application.

Specification

The abstract of the disclosure is objected to because the abstract is suppose to be only one paragraph. Presently, the abstract is comprised of three paragraphs Correction is required. See MPEP § 608.01(b).

Specification

The disclosure is objected to because of the following informalities: this application has only one figure, but the specification on page 72, line 18, refers to "Figure 8." Where is Figure 8? Is the figure 8 in Mostov's Nature article intended?

Appropriate correction/clarification is required.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claimed invention is directed to a PRODUCT not a method.

Claim Rejections - 35 USC § 112

Claims 80, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 80 is vague and indefinite for recitation of "protection protein", the intended metes and bounds of the protein is not defined. Is a ricin protein intended? The term "derived" in claim 80 is a relative term, which renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case, the definition of derivation has many meaning, therefore, the claim is considered as indefinite. In addition, the intended metes and bounds of the protein that is "derived" from a "polyimmunoglobulin receptor" is not defined. Moreover, the intended polyimmunoglobulin receptor is not defined. This affects claim 82.

Claim 82 is vague and indefinite for recitation of "plant produced", what is the intended plant. Is cacti intended?

Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP §

2172.01. The omitted steps are: transformation, types of plant i.e. transgenic or non, the conditions that would permit the production of antibody should be stated.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 80, and 82 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 12, 13, 29 of prior U.S. Patent No. 6,303,341 B1. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 80, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehner et al (WO 88/06455).

The claims and teaching of the above cited patent meets the broad limitations of the claimed invention (see claims 2-3). Applicants are reminded that antibodies are capable of long range of binding. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 80 is rejected under 35 U.S.C. 102(b) as being anticipated by Lehner et al (US patent no. 4,594,244, June 10, 1986).

The claims of the above cited patent meets the broad limitations of the claimed invention (see claims 1, 3, 6). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 80 is rejected under 35 U.S.C. 102(b) as being anticipated by Schlom (US Patent No. 5,183,756, 2/2/1993).

The claims and teaching of the above cited patent meets the broad limitations of the claimed invention (see claims 2, 8, 14). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 80 is rejected under 35 U.S.C. 102(e) as being anticipated by Lehner et al (5,854,402). The claims and teaching of the above cited patent meets the broad limitations of the claimed invention (see claim 1). Applicants are reminded that antibodies are capable of long range of binding. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of

performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehner et al (WO 88/06455), and Hiatt et al (US Patent No. 5,202,422, 4/13/1993).

Claim 82 is directed in producing antibodies in plants. Lehner et al as stated above taught the immunoglobulin (see claims) and Hiatt et al taught a method of producing immunoglobulin in plants (see claim 5). Hence, one of ordinary skill in the art would have been motivated to generate antibodies taught by Lehner et al (WO 88/06455), by utilizing the method of Hiatt et al (US Patent No. 5,202,422, 4/13/1993) in plants to be used in induction of immune response or diagnostic assay. The ordinary skill in the art would not have anticipated any unexpected result. Hence, the invention as a whole is considered to be prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

8/28/2002

ALI R. SALIMI
PRIMARY EXAMINER